

REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Upon entry of this Amendment, claims 43-58 and 60 will be pending in the present application. Claim 59 has been cancelled.

Claims 43-47 and 49 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,190,053 to Meer ("the '053 patent") in view of U.S. Patent No. 5,365,945 to Halstrom ("the '945 patent"). Method claims 50-54 and 56 are also rejected under 35 U.S.C. § 103 as being unpatentable over the '053 patent in view of the '945 patent. In addition, claims 48 and 55 stand rejected under 35 U.S.C. § 103 as being unpatentable over the '053 patent in view of the '945 patent in further view of U.S. Patent No. 4,414,982 to Durkan ("the '982 patent"). Applicant respectfully traverses these rejections for the reasons presented below.

The '053 (Meer) patent teaches an intra-oral appliance having a single support member 22 that supports a pair of electrodes 12 and 14. The support member engages the user's teeth and supports the electrodes such that both electrodes are placed at the floor of the mouth, with one electrode being provided on each side of the tongue. The '945 (Halstrom) patent teaches a dental appliance that maintains the mandible in an anterior protruded position to prevent airway obstruction.

Applicant notes that in citing these references, the Examiner has identified two techniques that are alleged useful for treating sleep apnea syndrome. Applicant further notes that other conventional techniques exist for treating this condition, such as positive pressure therapy, external tissue distension devices, implanted electrical stimulation, and surgical interventions. The present inventors recognized that the combination of mandibular advancement and non-invasive electrical stimulation provides an optimal treatment for this condition. Applicant submits that the one of ordinary skill in the art would not have considered it obvious to select these two particular treatment techniques and combine them.

According to the Examiner, “[it] would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Meer apparatus in view of Halstrom in order to maintain the patient’s mandible in a protruded manner, thereby averting obstruction of the pharyngeal pathway (Col. 4, ll 20-24).” This explanation falls short of giving a reason why one of ordinary skill in the art would consider it obvious to combine the two techniques. This explanation identifies the fact that Halstrom teaches a mandibular positioning technique and merely states that this technique could be used with the Meer electrical stimulation technique.

The fact that the mandibular positioning Halstrom technique averts obstruction of the pharyngeal pathway does not explain why it would be combined with electrical stimulation technique of Meer. The Meer electrical stimulation technique also attempts to avert obstruction of the pharyngeal pathway. If the Meer technique is successful, why would one of ordinary skill in the art seek to add the additional mandibular positioning technique of Halstrom? The converse is also true. If the Halstrom technique is successful, one of ordinary skill in the art would not consider is necessary to look to the alternative OSA treatment technique of Meer. Merely identifying the two techniques that the inventors considered optimal to combine, does not in itself explain why, absent the teaching of the present invention, these two treatments can or should be combined.

It is incorrect for the Examiner to formulate the suggestion or motivation based on current knowledge; the Examiner must remove all knowledge that he or she has accumulated since the date of invention. *Panduit Corp. v. Dennison Mfg. Co.*, 1 U.S.P.Q.2d 1593, 1595-96 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987). The Examiner must look at the prior art presented from a vantage point in time prior to when the invention was made, and through the eyes of a hypothetical person of ordinary skill in the art. *In re Carroll*, 202 U.S.P.Q. 571, 572 (C.C.P.A. 1979). Moreover, it is impermissible to use the claimed invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the

claimed invention.” *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992)(quoting *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)).

Applicant further notes that the Examiner should consider the totality of what one of ordinary skill in the art would have contemplated - knowing the various OSA treatment techniques that existed at the time of the invention. For example, one of ordinary skill in the art would have known that devices placed in the mouth should present as little material in the mouth as possible, because, generally, people do not want to sleep with devices in their mouth. Adding the Halstrom mandibular positioning technique to the Meer electrical stimulation device goes against this basic understanding held by one of ordinary skill in the art. Combining these techniques, which applicant does not admit would be obvious, only serves to increase the size of the oral appliance and makes it more complicated and costly. Again, why would one skilled in art combine two alternative treatments in parallel if doing so results in an oral appliance that is larger and bulkier? Applicant submits that one of ordinary skill in the art would seek to use some other OSA treatment technique, such as surgical intervention or a pressure support therapy, if the Meer electrical stimulation treatment was not sufficient, rather than combine the Meer and Halstrom techniques.

For the reasons presented above, applicant respectfully submits that independent claim 1 is not rendered obvious by the cited references. Independent claim 50 is a method claim that is generally similar to claim 1. Thus, the reasons why claim 1 would not be obvious over the cited references are equally applicable to claim 50. Claims 44-49 and 51-56 are also not rendered obvious due to their dependency from independent claim 43 or 50. Accordingly, applicant respectfully requests that the above rejections of claims 43-56 be withdrawn.

Claims 57-60 stand rejected under 35 U.S.C. § 103 as being unpatentable over the ‘053 patent in view of *In re Aller*, 220 F.2d 454,456, 105 U.S.P.Q. 233, 235 (C.C.P.A. 1955). Applicant respectfully traverses these rejections for the reasons presented below.

Independent claims 57 and 60 have been amended to clarify that the first support member and the second support member are configured and arranged such that the second electrode is disposed in a position posterior relative to the first electrode. Applicant submits that

the '053 patent does not teach or suggest providing this configuration for the electrodes. While *In re Aller* is concerned with the selection of ranges, claims 57 and 60, as amended are structurally distinguishable over the '053 patent. Moreover, these claims do not recite ranges, which is the subject matter that was at issue in *In re Aller*.

For the reasons presented above, applicant respectfully submits that independent claims 57 and 60 are not rendered obvious by the cited references. Claim 58 is also not rendered obvious due to its dependency from independent claim 57. Claim 59 has been cancelled, rendering its rejection moot. Accordingly, applicant respectfully requests that the above rejection of claims 57-60 be withdrawn.

This response is being filed within the three-month statutory response period which expires on September 17, 2007; the original three month due date of September 15, 2007 falling on a Saturday. In addition, no additional claim fees are believed to be required as a result of the above amendments to the claims. Nevertheless, the Commission is authorized to charge any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 50-0558.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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Note: The Commissioner is authorized to charge any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 50-0558.